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November 6, 2018

VIA ECF

The Honorable Renee M. Bumb, U.S.D.J. United States District Court for the District of New Jersey
Mitchell H. Cohen U.S. Courthouse
1 John F. Gerry Plaza, Room 2040
Camden, New Jersey 08101

Re: Genentech, Inc., Biogen, Inc. and City of Hope v. Sandoz, Inc., Sandoz International GMBH, and Sandoz GMBH Civil Action No. 17-13507 (RMB-KMW)

Dear Judge Bumb:

This firm, along with Sterne, Kessler, Goldstein & Fox PLLC, represents Defendants Sandoz, Inc., Sandoz GmbH, and Sandoz International GmbH (collectively "Sandoz").

The above-referenced case is based on an abbreviated Biologics License Application ("aBLA") for Sandoz's proposed biosimilar rituximab product. In response to Sandoz's aBLA, the U.S. Food and Drug Administration ("FDA") issued a Complete Response Letter ("CRL") on April 27, 2018, which means that resubmission of the aBLA would be necessary in order for Sandoz to proceed with its application for permission to market its proposed biosimilar rituximab product in the United States. As Your Honor will recall, the issuance of the CRL prompted the parties not to proceed with the planned preliminary injunction hearing planned for this past summer.

On November 2, 2018, Sandoz announced its decision not to pursue its submission for biosimilar rituximab in the United States at this time. Because Sandoz is not currently seeking FDA approval to market its proposed rituximab biosimilar product in the

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United States, we consider that the above-referenced action has become moot, as there is no longer a live case or controversy between the parties.

Sandoz respectfully requests that all remaining deadlines in the case schedule be stayed immediately. Sandoz has already conveyed news of the decision not to pursue its submission for biosimilar rituximab to Plaintiffs (collectively, "Genentech"), who have advised us that they consent to Sandoz's request to stay all remaining case deadlines. We have opened discussions with Genentech's counsel in the expectation of presenting the Court with a stipulation dismissing the case in the near future.

If the Court has questions or concerns, we stand ready to address them at the Court's convenience.

Respectfully yours,

/s Lisa J. Rodriguez
For SCHNADER HARRISON SEGAL & LEWIS LLP

LJR/mpw

cc: All Counsel (via ecf)